

Serial No. 10/007,177
5962-01-CA (PC17519)

I. AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

Claims 1-16 (canceled)

Claim 17 (currently amended) A method of making a pharmaceutical dosage form having an outer layer and a central core, the method comprising:

feeding components of said outer layer and said central core into first and second extruders, respectively, the outer layer components comprising a plasticizer and polymethacrylate or ethylcellulose;

coextruding an indefinite length of a melted or softened central core and outer layer from the second and first extruders, respectively, to form a co-extrudate having a longitudinal axis, said central core including a pharmaceutical agent disposed in a controlled-release composition, and said outer layer being substantially impervious to water or bodily fluids thereby limiting diffusion of fluids into said central core;

slicing said co-extrudate across the longitudinal axis thereof to form discrete pellets, each of the pellets having an exposed central core at opposite ends; and

cooling said co-extrudate to solidify the at least partially melted central core and outer layer.

Claim 18 (previously amended) The method of Claim 17, further comprising permitting said co-extrudate to harden before slicing said co-extrudate.

Claim 19 (previously amended) The method of Claim 17, further comprising slicing said co-extrudate perpendicular to said longitudinal axis.

Claim 20 (previously amended) The method of Claim 17, further comprising heating said co-extrudate to a temperature in the range of 30°C to 250°C during coextrusion.

Claim 21 (previously amended) The method of Claim 20, further comprising heating co-extrudate to a temperature in the range of 40°C to 200°C during coextrusion.

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Claim 22 (canceled)

Claim 23 (previously amended) The method of Claim 17, further comprising slicing said co-extrudate with a laser.

Claim 24 (canceled)

Claim 25 (previously added) The method of claim 17, wherein the first and second extruders are twin-screw extruders.

Claim 26 (new) A pharmaceutical dosage form comprising:

a central core including a pharmaceutical agent in a controlled-release composition, said core having two exposed opposite end surfaces and a peripheral surface extending between said two exposed opposite end surfaces;

a diffusion-limiting sleeve surrounding said peripheral surface, said diffusion-limiting sleeve being substantially impervious to water or bodily fluids thereby limiting diffusion of fluids into said core, the diffusion-limiting sleeve comprising a plasticizer and polymethacrylate or ethylcellulose;

wherein said pharmaceutical dosage form is formed by simultaneous melt extrusion of said central core and said diffusion-limiting sleeve.

Claim 27 (new) The pharmaceutical dosage form of Claim 26, wherein said matrix material comprises at least one material selected from the group consisting of polyethylene glycol, polyvinylalcohol, polymethacrylate, cellulose acetate phthalate, polyvinylpyrrolidone, hydroxypropylcellulose phthalate, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose acetate succinate, hydroxypropylcellulose, hydroxypropylethylcellulose, and polysorbate 80.

Claim 28 (new) The pharmaceutical dosage form of Claim 26, wherein the matrix material comprises polyvinylpyrrolidone and polyethylene glycol.